REMARKS

As noted on page 3 of the Examiner's action mailed November 6, 2001, the subject matter of claim 10 was objected to but was found to contain allowable subject matter and would be allowable if claim 10 were re-written in independent form. In Amendment B, filed February 21, 2002, claim 10 was so rewritten in independent form and was believed to be allowable. However, as indicated in the Examiner's action mailed March 28, 2002, Amendment B was not entered. Accordingly, on May 1, 2002, applicant filed a Request for Continued Examination (RCE) and submitted Amendment B. In the Examiner's action mailed May 21, 2002, the rejected claim 12 and 13 under § 112 and rejected claim 10 – 13 (all of the claims in the case) as being obvious over the prior art. In particular, claims 10, 11 and 13 were rejected over the combination of previously cited references and the newly cited patent to Weill (U. S. Patent 4,596,580).

Applicant herewith submits this Amendment which is believed to correct the §112 rejections. In addition, Applicant herewith submits the Declaration of Leo A. Whiteside, the inventor of the instant invention, which makes clear that the combination of the seal and the locking mechanism described in claims 10 – 13 are highly advantageous and are not suggested by the prior art of record. There is nothing in the prior art that would motivate one of ordinary skill in the art to combine the Parchinski, Schryver, and Weill references to result in the structure described by claims 10 – 13 and thus the subject matter described by these claims is properly allowable and should be allowed.

Correction of § 112 Rejections

Claim 12 was rejected under §112 as lacking antecedent basis if in specification. Specifically, the Examiner pointed out that the specification did not disclose "a plurality of tabs, one for each notch". However, as seen by comparing Figs. 1 and 4, there are an excess of notches 36 compared to the number of tabs 60 on the liner. In the passage of the specification quoted by the Examiner, there are, in fact, six tabs and twelve notches. Claim 12 has now been amended to specify that there is at least one notch for each tab. As noted, this is clearly shown in the drawing and thus there is proper antecedent support for claim 12.

In addition, claim 12, line 14 has been amended to omit the requirement the tabs snap fit in the notches.

In view of these amendments, it is submitted that claim 12 is now in compliance with § 112 and is now in proper form for allowance.

Claim Rejections - § 103

Claim 12 was rejected as being obvious over Parchinski (U. S. Patent 4,650,491) in view of Schryver (U. S. Patent 5,314,487). In addition, claims 10, 11, and 13 were rejected as being obvious over Parchinski and Schryver in view of Weill (U. S. Patent 4,596,580).

As will be set forth in detail herein and in the attached Declaration of the Inventor, Dr. Whiteside, the prosthesis of claims 10, 11 and 13 and the component for orthopedic joint replacement system of claim 12 describe new and

highly advantageous implant devices that overcome many long standing problems evidenced by the prior art.

Specifically, Dr. Whiteside states that these devices, as claimed, solve two major and long-standing problems theretofore experienced with prior similar devices. First, the seals in the claimed devices effectively prevent "joint fluid" from coming into contact with resected bone surfaces which leads to bone loss and loosening of the appliances. Secondly, the liners of these devices are securely locked to the metal component thereby preventing micro-motion movements of the liner with respect its metal component which leads to excess wear of the liner and which generates polyethylene debris which has been found to be detrimental to the service life of the prosthesis device. (Whiteside Declar. ¶ 6).

Specifically, in hip replacement systems, Dr. Whiteside has found that two of the most important features of such systems are: 1.) the provision of an effective seal between the interface of the polyethylene liner and the metal cup or shell, and 2.) a locking mechanism to insure that the polyethylene component is securely locked with respect to its shell so as to effectively prevent micro-motion movement of the liner with respect to the shell or housing as the patients walks or does other repetitive activities that subject the joint to movement or repeated weight bearing. (Whiteside Declar. ¶ 11).

In ¶ 12 of his Declaration, Dr. Whiteside points out that during the surgery, the metal component is typically installed on the bone and then the socket or

"polyethylene"[1]component is inserted into the metal component by the surgeon. Thus, not only is it necessary that the polyethylene component both be sealed and securely locked with respect to the metal component, but the installation of the polyethylene component must not require undue forces or time for the surgeon to install it in the metal component. The installation must be easy to do, it must effectively seal, and it must firmly lock the polyethylene component to the metal component. This seal and locking arrangement must hold up for millions of stress and weight bearing cycles.

In ¶s 13 – 15, Dr. Whiteside explains that common problems with joint replacement systems include the development of osteolysis (movement between the appliance or device and the bone structure to which the device is installed.). Another common problem is that joint fluid is driven into the bone proximate the joint causing cyst formation which leads to the loosening of the component which can lead to catastrophic loss of the supporting bone structure. Dr. Whiteside and others have found that this process of bone degeneration is worsened by screw holes or channels in the prosthesis device that allow the joint fluid to enter the bone stock supporting the metal shell of the device, whether the metal shell is attached to the bone by cement or by fasteners (e.g., bone screws).

Dr. Whiteside and others also found that that if the polyethylene liner was poorly fixed within its metal component (e.g., the shell), joint fluid could work behind the polyethylene component such that the joint fluid bathed the fixation

[1] Note, when the liner is referred to as a "polyethylene" component or liner, it is to be understood that in most conventional prosthesis devices one of the components is typically made of plastic, usually of a polyethylene material. However, by so referring to a polyethylene component, it is not meant to infer or limit in any way that this component must be made of polyethylene or any other particular material.

screws, and such the repeated stresses of walking and weight bearing would force the joint fluid under hydraulic pressure into the bone around the screws. This lead directly to loosening of the device and bone loss. (Whiteside Declar., ¶ 18).

In Paragraph 22, Dr. Whiteside states that one attempted solution to this long-standing problem of how to fix the polyethylene component to the metal component was to pre-assemble the polyethylene liner to its respective metal component at the factory to achieve rigid fixation of the polyethylene component and the metal component and to prevent the entry of joint fluid through the metal shell and the into the bone. However, these pre-assembled systems were difficult to affix to the bone in surgeries where the patient had experienced bone loss or had soft sub-surface bone structure.

In Dr. Whiteside's experience, he found that most polyethylene components are not rigidly affixed with respect to their respective metal components thus allow micro-motion between the polyethylene and metal components. This micro-motion causes the polyethylene component to wear and to shed microscopic particles which become entrained in the joint fluid and which can lead to damage to the implant. Moreover, all prior systems suffered from the lack of an effective seal. (Whiteside Declar., ¶ 23).

The lack of an effective seal against bone fluid leakage is particularly important because if there is excess joint fluid (which is often the case), the hydraulic pressure can be relatively high. The above-discussed micro-motion of the polyethylene component relative it its metal shell or housing can act as a

mechanical hydraulic pump so as to drive the fluid under pressure into the screw holes in the metal component and into the bone around the implant. (Whiteside Declar. ¶ 24).

To Dr. Whiteside's knowledge (and it is respectfully submitted that there is nothing in the prior art to refute Dr. Whiteside's following statement), the devices described in the claims of the instant reissue application achieve, for the first time, both rigid fixation of the polyethylene within its metal shell or housing, and an effective seal between the polyethylene component and its metal tray or shell. At the same time, the polyethylene component may be readily installed by the surgeon during the surgery after the metal component has been affixed to the bone with bone screws and the installation may be done quickly with reasonable insertion forces. Moreover, both the fixation and the seal remain in tact over a long service life in the patient. (Whiteside Declar. P 25).

Dr. Whiteside found that in order to be an effective seal, in order to have a rigid fixation, and in order to insure that only a low of force is needed to insert the liner into the metal component (which is typically done by the surgeon during the surgery after the metal component has been affixed to the bone structure), the seal must not only seal effectively, it must also be flexible to permit ease of insertion. As Dr. Whiteside points out in ¶ 27 of his Declaration, a flexible seal will readily deform to allow easy insertion. A flexible seal will sealingly mate with its sealing surface on the metal component. A flexible seal will maintain sealing relation through a million stress cycles, such as the prosthesis device will experience upon the patient walking over the life of the patient. However, a

flexible seal cannot be used to restrain or lock movement of the liner with respect to the shell. It is for that reason that a separate seal and a separate fixation system must be employed. Of course, these are features that are described in claims 1- 1- 3 of the instant reissue application.

Dr. Whiteside's Observations, As One Of Ordinary Skill in the Art, Regarding The Disclosures of the Prior Art and Testing Done By Dr. Whiteside That Show His Claimed Devices Overcome Long-Standing Problems of the Prior Art.

As detailed in Dr. Whiteside's Declaration (see ¶s 36 et seq.), Dr. Whiteside has carried out research and testing on the devices as described in the claims of this reissue application and on devices similar to that described in Parchinski, Weill, and Schryver. Dr. Whiteside has found that these prior art devices do not have the features of his claimed invention.

First, Dr. Whiteside points out that neither Parchinski nor Schryver disclose a prosthesis component that has both a seal and an effective locking system. (Whiteside Declar. ¶ 29).

As the title of Parchinski states, that invention relates to a "Locking System For Prosthesis Components". The prosthesis component described in Parchinski is an acetabular component for a total hip replacement system. It includes a metal shell or cup 12. However, it is noted that the shell 12 of Parchinski is not affixed to the bone structure by means of bone screws. Instead, as described in Col. 2, lines 38 et seq., "The outer surface of shell 12 includes a self-tapping thread 16 which allows prosthesis 10 to be inserted into an acetabulum (not shown) without the use of bone cement."

The locking mechanism described in Parchinski is described (at Col. 2, lines 63 et seq. – Col. 3, line 20) as a first annular circumferential rib 38 on the cylindrical portion of the polyethylene insert 14 which is congruent with groove 28 in the interior of the metal shell 12, and a second rib 40 proximate rib 38. As disclosed at Col. 3, line 8 et seq., "when insert 14 is fully assembled within shell 12 as shown in Fig. 5, rib 38 snaps into groove 28 while rib 40 is deformed or flexed and pressed against concavity 18. This latter interference action insures a positive resistance to axial movement or chatter of insert 14 within shell 12 which the combination of rib 38 within groove 28 alone cannot provide. This interference action of rib 40 against concavity 18 also insures positive resistance to rotational chatter of insert 14 within shell 12."

Moreover, Parchinski discloses that "the polar region of shell 12 [is] removed to provide a large circular opening 26 for allowing visual assessment of bone apposition during insertion of shell insertion into the acetabulum." (Col. 2, lines 44 – 47). Dr. Whiteside states that this opening 26 constitutes a direct path for joint fluid to come into contact with the bone structure unless the polyethylene component 14 is effectively sealed with respect to the metal shell 12. (Whiteside Declar. ¶ 32). Yet, there is no mention whatsoever in Parchinski of the need for a seal between the two components, nor is there any mention that the disclosed locking mechanism performs a sealing function.

As Dr. Whiteside points out in ¶ 33 of his Declaration, one or ordinary skill in the art, in 1995 when my patent application was filed would recognize from

reading the disclosure of Parchinski, that Parchinski did not even recognize the need for a seal.

Moreover, Dr. Whiteside states that it has been his experience, as one who has invented, designed, developed, tested and used a variety of orthopedic appliances, that the deformable locking rib 40 of Parchinski would not inherently both prevent axial and rotational chatter, as is expressly disclosed in the Parchinski patent, and effectively seal the polyethylene liner 14 with respect to the shell 12. The reason for this is that in order to prevent movement or chatter, the rib 40 must be relatively stiff. However, such a stiff rib design will not have sufficient flexibility to effect a seal. These two functions are counter to one another. (Whiteside Declar. ¶s 34, 35).

Dr. Whiteside points out a paper that he co-authored entitled "Effect of Locking Mechanism on Fluid and Particle Flow Through Modular Acetabular Components", as published in The Journal of Arthroplasty, Vol. 13, No. 3, 1998 (pages 254 – 258), a copy of which is attached to Dr. Whiteside's Declaration as Exhibit 1. The research for this paper was conducted by Dr. Whiteside's company, Whiteside Biomechanics, Inc., in part by Dr. Whiteside by the other co-authors of the paper. (Whiteside Declar. ¶ 36).

The purpose of this testing was to determine whether commercially available acetabular components (as listed on page 255 of Exhibit 1) offered a route for joint fluid and debris through the screw holes into the acetabular bone stock. One of the components tested was Whiteside Biomechanics, Inc.'s. Micro Seal ® acetabular component that is the subject of the above-reissue application.

The construction of the Micro Seal ® locking tab and seal of the polyethylene liner are shown in Fig. 1 of the paper. It is seen that this photo (Fig. 1 of the paper) is similar to Fig. 5 of this reissue application. (Whiteside Declar. ¶ 37).

Dr. Whiteside is familiar with hip joint sockets similar to that described in U. S. Patent 4,596,580 to Weill which is assigned to Protek AG of Switzerland. It will be noted that the appliance described in Weill uses a plastic socket member 1 in the general form of a truncated cone. The socket 1 is received in a metal ring member 8 which has a female tapered opening for receiving the tapered conical surface of the socket member 1. As shown in Fig. 1 of the Weill patent, the plastic socket member 1 has four (4) tabs 10 extending radially therefrom. Each of these tabs is received in a respective recess 11. As shown in Fig. 3, each of the tabs 10 is generally of trapezoidal shape having generally horizontal upper and lower surfaces (not numbered) and upwardly and inwardly sloping side surfaces (also not numbered). The corresponding side surfaces of recess 11 also slope upwardly and inwardly of the recess. (Whiteside Declar. ¶ 38).

Dr. Whiteside points out that upon installation of the socket member 1 into the metal ring member 8 of Weill, with the tabs 10 aligned with their respective recesses 11, the bottom surface of the tabs will be wider than the narrow opening of the recess formed by the upwardly and inwardly sloping side surfaces of the recess. Accordingly, in order to insert the tabs into the recess, the plastic tabs must be deformed such that the tabs will forcibly enter the recesses. As can be appreciated from viewing the relative dimensions of the tabs and the recesses in Fig. 3 of Weill, there must be considerable deformation of the tabs to enable

insertion into the recesses. Of course, there are four (4) such tabs and recesses used with the device disclosed in the Weill patent and all four of these tabs must be substantially simultaneously inserted into their respective recesses in order to maintain axial alignment of the socket with respect to its ring member. This will require four times the insertion force of a inserting a single tab into a single recess. Thus, the force required to insert the socket into its ring member would be unduly high if the socket were required to be installed in the ring member during surgery after the ring member had been installed on the bone structure. However, because the appliance of Weill does not require bone screws for attachment, it may not be necessary that the socket needs to be installed by the surgeon during surgery, but instead could be factory assembled in which case the high insertion forces would not be a problem. (Whiteside Declar. ¶ 39).

Further, with regard to the Weill patent, Dr. Whiteside points out that in Fig. 2 of the Weill patent, the bottom end of the plastic socket member 1 extends completely through the tapered opening of the metal ring member 8. He also notes that there is no seal, other than the taper surface to tapered surface engagement of the socket within the ring member, that would effectively prevent the migration of joint fluid or debris to the bone structure at the bottom end of the appliance. (Whiteside Declar. ¶ 40).

With respect to the appliances tested by Dr. Whiteside and by the co-authors of Exhibit 1, one of the devices tested did have a similar ring and socket member with tapered surfaces similar to what is described in the Weill patent and such appliance did employ the taper locking system as shown in the Weill patent

and as described above. This tapered locking system did not have an effective seal for preventing the migration of joint fluid and debris. (Whiteside Declar. ¶ 41).

Dr. Whiteside also points out that as stated in Exhibit 1, one of the appliances tested was a "Reflection Cup" manufactured by Smith & Nephew of Memphis, TN. Dr. Whiteside states that he reviewed U. S. Patent 5,314,487 invented by Mr. Schryver et al. which is assigned to Smith & Nephew. Dr. Whiteside attest that the "Reflection Cup" appliance tested in Exhibit 1 is manufactured by Smith & Nephew and is similar in construction to the appliance described in the Schryver patent. (Whiteside Declar. ¶ 42).

In this testing, as described in detail on pages 255 and 256 of the above paper (Exhibit 1), each of the acetabular components was installed in the test setup shown in Figs. 2 and 3 of Exhibit 1. The upper chamber was pressurized to a level of about 300 mm of water and repeated axial and torsional loads were applied using a servo-hydraulic Instron testing machine. The water used to pressurize the upper chamber contained micro-spheres of polystyrene so that it could be seen whether debris, as well as water which was used to simulate joint fluid, would flow through the interface between the polyethylene component and its shell and thus come into contact with the bone structure. This cyclical loading was applied some 1,000,000 times. The only route for the water between the upper chamber and the lower chamber was through the interface between the polyethylene liner and its shell. (Whiteside Declar. ¶ 43).

As a result of this testing, it was determined that the seal around the rim of the Micro Seal ® of the Whiteside polyethylene component (which had the seal and locking structure described in the claims of this reissue application) effectively prevented fluid and particle flow between the metal shell and the polyethylene liner. However, all of the other devices tested passed water and the polystyrene micro-spheres through the liner-to-shell interface and into the collection chamber, except Smith & Nephew's Reflection cup which had a cover in the screw holes. (Whiteside Declar. ¶ 44).

Importantly, in Paragraph 45 of his Declaration, Dr. Whiteside states that with his seal design, only modest forces are required to install the liner within the acetabular shell after the latter has been affixed to the pelvic bone structure with bone screws. These low inserting forces are due in large part to the flexible nature of the seal.

The reason that low insertion forces are necessary is that the patients undergoing joint replacement surgery generally have a de-generative bone or joint disease that oftentimes significantly weakens the bone stock supporting the prosthesis components. If high forces are required to install the liner within its metal shell, the bone stock may be very weak and the high insertion forces may cause the bone stock to fail which could put the entire joint structure in jeopardy.

Dr. Whiteside has found that the structure of the seal as shown in Fig. 5 of his reissue patent and as described in claims 10 and 12 of this reissue application makes for low insertion forces. This is due to the fact that the seal is flexible. (Whiteside Declar. ¶ 47).

Further, Dr. Whiteside states that the separate locking tabs and the notches in the shell, as described by the claims of this reissue application, effectively fix the polyethylene liner rigidly within the metal shell thus preventing micro-motion between the shell and the liner. Moreover, the locking tabs and notches, as described in the claims of the instant reissue application, result in low insertion forces that will not cause damage to the bone stock and that will not require the surgeon to use undue force. (Whiteside Declar. ¶ 48).

In contrast, upon reviewing the locking tabs and notches disclosed in the newly cited U. S. Patent 4,596,580 to Weill, Dr. Whiteside states that it would appear that a very high level of insertion force would be required to snap-fit the four (4) tabs or "outwardly extending parts 10" of the socket member 1 into their "correspondingly shaped recesses 11" of the ring member 8. (Whiteside Declar. ¶ 49).

As can be best seen in Fig. 3 of Weill, the notch 11 in ring member 8 has sides 14 which slope downwardly and outwardly of the notch such that the notch is narrower at its top than at its bottom. Likewise, the tab 10 formed on the socket member 1, has sides (not numbered) which slope downwardly and outwardly such that the widest dimension of the tab 10 is at its bottom. Thus, upon insertion of the tabs into the notches, when the tabs are initially aligned with their respective notches, the widest dimension of the tabs will first encounter the narrowest dimension of the notch. This will require significant deformation of the tabs (which as disclosed in Weill at Col.1, line 14) are "frequently made of plastic" such that they will snap fit in the notches. It will be borne in mind that since Weill

discloses that the tabs 10 are spaced equally at 90 °, there will be four of the tabs that must substantially simultaneously inserted into their notches. This will multiply the force required for insert by a factor of 4. It is my view that this may well result in the surgeon having to apply unduly high levels of force to insert the socket member 1 into the ring member 8 which could damage the supporting bone stock on which the ring member is installed.

Importantly, Dr. Whiteside states in Paragraph 51 of his Declaration, that even as of the present date in 2002, some 7 years after the original filing date of this application, the design described in claims 10 and 12 of this reissue application is the only such design that achieves a good seal and yet rigidly fixes the polyethylene component within the shell.

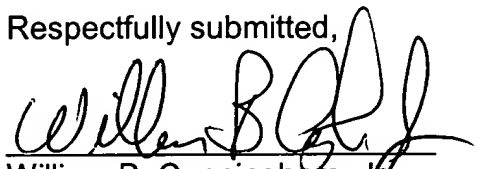
In view of the above and in view of the research done by Dr. Whiteside and as reported in his Declaration and in Exhibit 1 attached thereto, it is respectfully submitted that there has been a long-standing problem with the prior art devices similar to those described in the Parchinski, Schryver, and Weill references. While the Examiner has suggested that it would be obvious to combine certain features of the prior art to result in the structure described by the claims of the reissue patent application, it is respectfully submitted that the Examiner has not pointed out to any teaching or suggestion in these prior art references that would motivate one skilled in the art to make changes suggested by the Examiner.

Accordingly, it is submitted that claims 10 – 13, particularly as herewith amended to correct the § 112 problems pointed out by the Examiner are properly allowable.

The amendments made herein are in the nature of clarifying amendments and further emphasize and contrast the novel structure of applicants' invention relative to the prior art. The entry of these amendments requires no new search, raises no new issue, and requires no substantial amount of additional work by the U.S. Patent and Trademark Office. The entry of these amendments is necessary and proper inasmuch as they are believed to place the application in form for allowance. These amendments could not have been made earlier because they were necessitated to a large degree to the Examiner's rejections, as listed in the May 21, 2002 Examiner's action.

In view of the foregoing, withdrawal of the final rejection, entry of these amendments, and a formal notice of allowance of claims 10 - 13 are requested. If for any reason the application is not held to be allowable, entry of these amendments for the purpose of appeal is hereby requested.

Respectfully submitted,



William B. Cunningham, Jr.
Reg. No. 26,155
Polster, Lieder, Woodruff & Lucchesi
763 South New Ballas Road
St. Louis, MO 63141
Telephone 314-872-8118
Fax No. 314-991-2178

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Leo A. Whiteside
SERIAL NO.:	09/595,352
FILED:	June 15, 2000
EXAMINER:	Bruce E. Snow
DOCKET NO.:	WBC 7403US
GROUP ART UNIT:	3738

FOR: Acetabular Component With Improved Liner Seal and Lock

APPENDIX
AMENDMENT
VERSIONS WITH MARKINGS
TO SHOW CHANGES MADE

In the Claims:

Please amend the claims as follows:

10. A prosthesis comprising:

a shell having at least one screw hole formed therein and a smooth inner sealing surface;

a liner configured to seat within said smooth inner surface of said shell, said liner including at least one circumferential peripheral annular seal flexibly and sealingly engaging said smooth inner sealing surface of said shell to restrict migration of debris toward said at least one screw hole;

said shell having a plurality of peripheral notches therein; and

said liner having a plurality of tabs extending outwardly from the liner with each tab being received in a respective one of said notches in said shell, each said notch having a pair of inwardly projecting lips to grasp its respective said tab.

12. A component for an orthopedic joint replacement system, said component comprising a metal shell adapted to be affixed to a bony structure within the human body by means of bone screws [or the like], said shell having one or more holes therein for reception of said bone screws and an inner surface, a liner of a suitable synthetic resin material adapted to fit closely within said inner surface of said shell, said liner constituting a bearing surface for another component of said joint replacement system, said liner having at least one flexible seal extending outwardly from said liner for sealing engagement with said inner surface of said shell around the entire liner so as to prevent the migration of joint fluid and debris from said joint to said screw holes, said seal being configured so as to flex [be flexible] upon insertion of said liner into said shell after said shell has been affixed to said bony structure by said bone screws, said liner further having a lock separate from said seal, said lock comprising a plurality of notches in [the] an upper peripheral edge of said shell and a plurality of tabs, at least one notch for each said [notch] tab, said tabs extending outwardly from said liner and being adapted to be [snap-fit] received in said notches upon installation of said liner into said shell, each said notch having a

pair of inwardly sloping sidewalls cooperating with said tabs so as to substantially inhibit micro motion between said liner and said shell.

13. The prosthesis of claim 10 wherein each of said tabs has a rounded surface and an flat surface, wherein said rounded surfaces bear on the base of said recess and wherein [the tops of said tabs are rounded so that] said lips engage said flat surface [rounded tops] of said tabs as the tabs are received within said notches.